510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA. 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

NOV 1 2 2013

5. **Date:** November 7, 2013

6. **TRADE NAME(S):**
   XIDF-AWS801; Angiography Workstation

7. **COMMON NAME:**
   System, X-ray, Fluoroscopic, Image-Intensified

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1650)

9. **PRODUCT CODE / DESCRIPTION:**
   JAA; System, X-ray, Fluoroscopic, Image-Intensified

10. **PERFORMANCE STANDARD:**
    21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

11. **PREDICATE DEVICE:**
    Toshiba Dose Tracking Software – K123097
    Toshiba XIDF-AWS801 Angio Workstation – K120073

12. **REASON FOR SUBMISSION:**
    Modification of a cleared device

13. DEVICE DESCRIPTION:

The XIDF-AWS801 Angio Workstatoin is a workstation for post-processing software that displays images in 2-d or 3-d format to provide additional information to the clinician. The software on this device remains unchanged with the exception of XIDF-DTS802 software.

The dose tracking system (DTS) is an application software package intended to provide the estimated dose distribution information during radiographic and fluoroscopic procedures. The dose tracking system (DTS) calculates the radiation dose of the patient's skin using the exposure technique parameters and exposure geometry obtained from the x-ray imaging system and presents the cumulative results in a color mapping on a 3D graphic of the patient model.

14. SUMMARY OF INTENDED USES:

The Angio Workstation is used in combination with an interventional angiography system (Infinix-i series systems and INFX-8000V and INFX-8000C systems) to provide 2D and 3D imaging and Dose Tracking System functions in selective catheter angiography for the heart, chest, and abdomen.

15. SUBSTANTIAL EQUIVALENCE:

The change to the device is to provide the Dose Tracking Software (DTS) which was market cleared via K123097. Additionally, functionality has been added to the DTS which has been verified with the same test methodology as previously reported to the Agency. The added functionality includes use during general angiography and radiography procedures, as well as expanded C-arm position dose estimations. The addition of this functionality does not change the intended use of the DTS as the device remains intended to provide real-time dose estimation.

In summary both the intended use and the test methodology remain unchanged for the subject devices of this submission. Toshiba believes that substantial equivalence has been established.

Table 1 System configuration (Hardware requirements)

ITEM	Image processor XIDF-AWS801	Image processor XIDF-AWS801 with Dose Tracking System XIDF-DTS802
510(k) Number	K120073 (INFX-8000V)	
Intended use	This device is used for images input from Diagnostic Imaging System and Workstation, image processing and display. The processed images can be outputted to Diagnostic Imaging System and Workstation. This device provides the image information and measurement results that are required when performing Angiography Procedures.	The same
Standard hardware configuration	PC, Monitor, HUB, Keyboard, Mouse, Calibration unit	The same
Option hardware configuration	CAN I/F card and cable	The same
Standard Software	3D reconstruction	The same
Option Software	3D Roadmap Multimodality Roadmap TAVR support	3D Roadmap Multimodality Roadmap TAVR support Dose Tracking System kit

Table 2. Predicate Device Comparisontable

ITEM	Dose Tracking System XIDF-DTS801	Dose Tracking System kit XIDF-DTS802
510(k) Number	K123097	
Configurations		
Type of device	Software	Software
Required hardware	PC is required	XIDF-AWS801
< Intended use >		
Indications for use	DTS is intended to display an approximation of both skin dose distribution and skin dose rate in real time during fluoroscopic interventional procedures of cardiac angiography. This software is intended for use on the Toshiba INFX-8000F CSi cardiac labs.	DTS is intended to display an approximation of both skin dose distribution and skin dose rate in real time during fluoroscopic interventional procedures and radiographic procedures.
Intended procedures	Cardiac angiography	Cardiac angiography General angiography All radiography exposures
Intended patient information	Male: Height from 130 cm to 200 cm Female: Height from 117 cm to 187 cm	Male: Height from 130 cm to 200 cm Female: Height from 117 cm to 187 cm Child: Height from 50 cm to 150 cm
Systems[1]	INFX-8000F	INFX-8000V INFX-8000C

ITEM	Dose Tracking System XIDF-DTS801	Dose Tracking System kit XIDF-DTS802
<Software functionality>		
Basic algorithm to calculate skin dose	Available	Almost same
Compensation for deep C-arm angle to calculate skin dose	Available	Available (Improved)
Compensation for field of view to calculate skin dose	Not available	Available
Displayed height and weight information on patient model select window.	Not available	Available
Report viewer	Not available	Available

[1] When applied to dual arm systems only frontal arm can display the DTS results

16. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards and its collateral standards. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

17. SUMMARY OF TESTING:

Testing was performed using anthropomorphic phantoms and Lexan phantoms to verify and validate the performance of the system. Based upon this testing the accuracy of the displayed estimated dose was determined and is included in the user information.

18. CONCLUSION

The addition of the XIDF-DTS802 Dose Tracking Software that is being added to the XIDF-AWS801 Angio Workstation at this time does not change the indication for use or the intended use of the device. Safety and effectiveness have been verified via risk management and application of design controls to this modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780-2068

Re: K132106
Trade/Device Name: Infinix Angio Workstation W/dts Software
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: October 11, 2013
Received: October 15, 2013

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132106

Device Name
XIDF-AWS801; Angio Workstaton w/Dose Tracking System

Indications for Use *(Describe)*
The Angio Workstation is used in combination with an interventional angiography system (Infinix-i series systems and INFX-8000V and INFX-8000C systems) to provide 2D and 3D imaging and Dose Tracking System functions in selective catheter angiography for the heart, chest, and abdomen.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*